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EXAMINER	
FORD, ALLISON M	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 10/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/822,222	SCHMITT ET AL.	
	Examiner	Art Unit	
	Allison M. Ford	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments/Amendments

Amendments to claims 1, 6, 18, 24, 29, and 32, received in the reply filed 6 September 2005 have been entered. Claims 37-49 have been cancelled. Claims 1-36 remain pending in the current application.

Applicant's arguments with respect to claims 1-36 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 29-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant's claim 29 is directed to a method of producing a hydrolyzed lecithin product, comprising phospholipids, monoglycerides, and diglycerides, the method comprising contacting a lecithin material, comprising a phospholipid component and a triglyceride component, in an aqueous or organic solvent, with a lipase effective to selectively hydrolyze the triglyceride, in the absence of a phospholipase. However, this method appears to be repugnant to the teachings in applicant's specification; applicant's specification teaches an enzyme that selectively hydrolyzes a triglyceride does not hydrolyze a phospholipid (such as lecithin) (See Spec, Paragraph 0077). Therefore applicant's specification teaches away from effectively hydrolyzing the phospholipid (lecithin) component of the 'lecithin material' to

create the hydrolyzed lecithin products, if there are no steps of contacting the material with an enzyme that is capable of hydrolyzing lecithin. Applicant's have not enabled one of ordinary skill in the art to hydrolyze the phospholipid component (lecithin) of 'lecithin material' with a lipase that selectively hydrolyzes the triglyceride component of 'lecithin material,' and without a phospholipase. One of ordinary skill in the art recognizes that phospholipids, such as lecithin, are hydrolyzed by phospholipases and general acting lipases (See, e.g. Haas et al (1995), Pg. 519, col. 2); however, a lipase that is specific to triglycerides will not hydrolyze lecithin, as triglycerides and lecithin are different and distinct molecules. Addition of lipase to a mixture of lecithin and triglycerides would produce mono- and diglycerides, as lipase will hydrolyze the *triglycerides* to mono- and diglycerides (as appears to be done in Example "F" of the specification), but it is inappropriate to refer to the mono- and diglycerides from hydrolyzed triglycerides as 'hydrolyzed *lecithin products.*' Though mono- and diglycerides are also products of the hydrolysis of lecithin, the mono- and diglycerides formed by the method claimed in claims 29-36 are not hydrolyzed *lecithin* products, but hydrolyzed *triglyceride* products.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant's claims 1 and 18 are directed to a method of producing a hydrolyzed lecithin product, comprising hydrolyzed phospholipids, monoglycerides, and diglycerides, the method comprising (a) contacting a lecithin material, comprising a phospholipid component and a triglyceride component, in either an aqueous solvent medium or in an aprotic organic solvent medium with a first enzyme effective to hydrolyze the phospholipid; and (b) subsequently contacting the product of step (a) with a second

enzyme, different from said first enzyme, said second enzyme being a lipase effective to hydrolyze said triglyceride.

Applicant's claim 29 is directed to a method of producing a hydrolyzed lecithin product, comprising contacting a lecithin material, comprising a phospholipid component and a triglyceride component, in an aqueous or organic solvent medium, with a lipase effective to selectively hydrolyze the triglyceride, in the absence of a phospholipase.

Applicants have pointed out in their response that the examiner's initial interpretation of 'a phospholipid component' and 'a triglyceride component' of the 'lecithin material' was incorrect; rather applicant states that a 'lecithin *mixture'* is to comprise both lecithin (which applicant appears to refer to as a 'phospholipid component' and separate triglycerides (which applicant appears to refer to as a 'triglyceride component'). Though in applicant's response they refer to a 'lecithin *mixture*' this term is not used through the original disclosure, but rather the term 'lecithin *material*' is used.

However, this definition provided by applicant is unclear. Lecithin is a single molecule, also referred to as phosphatidylcholine (See "Lecithin" Wikipedia; JBC (1960) Hanahan et al , Pg. 1923; & Garrett et al "Biochemistry" Pg. 246). As noted in applicant's specification, phospholipase A1, phospholipase A2, phospholipase C and phospholipase D effectively hydrolyze lecithin to produce hydrolyzed lecithin (See Spec, Pg. 12). As applicant has pointed out in their remarks, phospholipids, such as lecithin, and triglycerides are distinct molecules.

Defining "lecithin material" as a combination of lecithin (which applicant calls phospholipids) and triglycerides is repugnant to the art accepted definition for lecithin. If applicant is intending to define 'lecithin material' as more than lecithin, it must be made clear throughout the entire application. As noted above, lecithin is a single molecule, technically referred to as phosphatidylcholine; therefore a lecithin *material* would not comprise additional triglycerides. If applicant intends for the claims to be directed to a mixture *comprising* both lecithin and triglycerides, they may refer to the lecithin (or phospholipid)

component of the mixture, and to a separate triglyceride component of the mixture. However, as written, and as described in the specification, it is not clear how applicant is defining a "lecithin material" to comprise any molecules besides lecithin (phosphatidylcholine). It is also noted that in the examples provided in the specification applicant's merely use 'fluid lecithin' there is no mention of inclusion of additional triglycerides, or presence of any natural triglycerides; therefore it is not clear if applicants do intend to require 'lecithin material' to comprise triglycerides.

Also, the body of the claims do not appear to be commensurate in scope with the preambles. The preambles recite a method intended to produce hydrolyzed *lecithin products*; however, while the addition of the first enzyme functions to hydrolyze *lecithin*, the addition of the second enzyme functions to hydrolyze *triglycerides*. If applicant's claimed methods are intended to produce hydrolyzed *lecithin products*, addition of the second enzyme in order to hydrolyze the triglycerides, is not required, as the lecithins are hydrolyzed solely by the first enzyme. Therefore the purpose of contacting the product of the first reaction with a second lipase to effectively hydrolyze the triglycerides, is not clear and does not appear to have substantial utility.

Claims 11, 25, and 31 require the 'lecithin material' to be a retentate from a vegetable oil membrane degumming process. Degumming processes, by definition, functions to refine crude oils by separating phosphatides (such as lecithin) from triglyceride oils (See, e.g. Paulitz et al, col. 1, ln 15-17); thus the retentate from the vegetable oil membrane degumming process would comprise phosphatides including lecithin, but it would not comprise the triglycerides. Therefore the retentate from a degumming process would not be suitable for applicant's claimed methods, which requires a composition comprising both phospholipids and triglycerides (which applicant calls a "lecithin material").

Claim 17 is further rejected as being self-dependent. The metes and bounds of the claim cannot be determined.

Applicant's claim 29 is directed to a method of producing a hydrolyzed lecithin product, comprising phospholipids, monoglycerides, and diglycerides. Applicant has defined lecithin as a phospholipid; therefore it is unclear how the hydrolyzed lecithin products comprise phospholipids. Applicant needs to clearly differentiate between the two types of phospholipids.

Claim 29 is further unclear because it requires producing hydrolyzed lecithin product but prohibits exposure of lecithin to a phospholipase, rather it only requires contact of the composition with a lipase that will selectively hydrolyze the triglyceride. Applicant's specification teaches an enzyme that selectively hydrolyzes the triglyceride does not hydrolyze a phospholipid (such as lecithin) (See Spec, Paragraph 0077); therefore it is not clear how the method effectively *produces hydrolyzed lecithin products* if there are no steps of contacting the material with an enzyme that is capable of hydrolyzing lecithin.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 29 is rejected under 35 U.S.C. 102(b) as being anticipated by Bojsen et al (US 2003/0175383).

Bojsen et al teach a method of preparing a flour dough, which comprises a phospholipid component and a triglyceride component, by contacting the flour dough with a lipolytic acyl hydrolase (LAH E.C. 3.1.1.26) (See Pg. 2-3, paragraph 0042). LAH is a lipase that effectively hydrolyzes phospholipids, including phosphatidylcholine (lecithin) to create hydrolyzed phospholipids, but does not hydrolyze the triglyceride or 1-monoglyceride components of the flour dough (See Pg. 2-3, paragraph

0042 and Pg. 3 paragraph 0057-0058 (Claim 29). Therefore the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4-6, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yasukawa et al (US Patent 4,976,984), in view of Hattori et al (US Patent 5,378,623).

Yasukawa et al teach a method for making an edible oil and fat composition comprising phospholipids and a glyceride mixture, wherein the glyceride mixture comprises diglycerides, monoglycerides and triglycerides, the method comprising hydrolyzing natural lecithins with enzymes such as phospholipase D and phospholipase A2 to produce phospholipids and other hydrolyzed lecithin products (See col. 4, ln 24-44); in a separate reaction, hydrolyzing triglycerides with digestive enzymes such as 1- and 3-site selective lipase to produce a glyceride mixture of mono-, di-, and triglycerides (See col. 6, ln 24-57); and combining the hydrolysis products to produce the edible oil and fat composition (See col. 6, ln 56-62). Yasukawa et al teach the phospholipid component of the final composition should comprise about 0.1 to 30% by weight, preferably 0.3 to 20% by weight phospholipid (See Yasukawa col. 6, ln 56-62).

Though Yasukawa et al teach hydrolyzing the lecithin and triglycerides separately, and then combining the hydrolyzed products, it would have been obvious to one of ordinary skill in the art at the time the invention was made to alternatively combine the lecithin and triglyceride, and then add, either simultaneously or sequentially, the enzymes used to hydrolyze the products (phospholipase A2 and/or

phospholipase D and lipase). One of ordinary skill in the art would have been motivated to combine the lecithin and triglycerides and perform the hydrolysis in a single container in order to reduce the amount of glassware and containers required for the reaction. Regarding the order or sequence of adding the hydrolysis enzymes, it is a well recognized principle in patent law that selection of any order of performing process steps and selection of any order of mixing ingredients is prima facie obvious without showings that the claimed order is critical or produces unexpected results, see *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) and *In re Gibson*, 30 F.2d 975, 5 USPQ 230 (CCPA 1930). One would have had a reasonable expectation of successfully creating the desired fat and oil composition, comprising phospholipids and glyceride mixture, because one would not expect the function of phospholipase A2, phospholipase D, or lipase to have any effect on the function of other enzymes, as they cleave different portions of the molecules, thus no competitive inhibition would be expected. In fact, one would have a reasonable expectation that the lipase enzymes would aid in the hydrolysis of the lecithin molecules, in addition to hydrolysis of the triglycerides, to produce a greater degree of hydrolyzed phospholipids (Claims 1, 4, 5, 6, and 14).

Additionally, though Yasukawa et al only teach the use of phospholipase A2 and phospholipase D to hydrolyze the lecithin, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use any enzyme that effectively hydrolyzes an ester bond in a phospholipid, including phospholipases A1, A2, C, D, and/or lipase (See Hattori et al, col. 1, ln 11-28). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use any combination of the enzymes mentioned above, in any order, to hydrolyze the lecithin to produce the hydrolyzed lecithin products (Claims 4 and 15). One of ordinary skill in the art would have been motivated to contact the lecithin in the composition of lecithin and triglycerides with any or all of the enzymes capable of hydrolyzing the lecithin material. One would have been motivated to contact a lecithin material with any or all of the enzymes mentioned above in any order to produce a hydrolyzed lecithin materials useful in

the edible fat and oil composition of Yasukawa et al. It is well known in the art that phospholipase A1, A2, C, D and lipase all hydrolyze ester bonds within phospholipid molecules to produce hydrolyzed phospholipids, mono- and diglycerides in various proportions and structures that could be used in the composition of Yasukawa et al (See, for example, Hattori et al). One of ordinary skill in the art would be motivated to use the enzymes in any combination and order because the enzymes, especially the phospholipases, have specific cleavage sites, the use of one enzyme does not effect the action of another enzyme. The reaction product of a first enzyme with the lecithin material is not necessary for subsequent hydrolysis by different enzymes. For example, if one was using enzymes immobilized on stirs, and contact with the lecithin material involved stirring the lecithin material with the enzyme-coated stir, it would be a matter of design choice which order one wished to use the various enzyme-coated stirs. One would expect success producing the hydrolyzed lecithin product claimed using any or all of the enzymes described above because the exact proportions and structures of the hydrolyzed products are not important, only that the resulting product is hydrolyzed lecithin and glyceride mixtures. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 2, 3, 7-10, 16-24, and 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yasukawa et al (US Patent 4,976,984), in view of Hattori et al (US Patent 5,378,623), Sas et al (US Patent 6,068,997), Haas et al (J. Am. Oil Chem. Soc, 1995) and Chung et al (US Patent 6,773,902).

Yasukawa et al teach a method for making an edible oil and fat composition comprising phospholipids and a glyceride mixture, wherein the glyceride mixture comprises diglycerides, monoglycerides and triglycerides, the method comprising hydrolyzing natural lecithins with enzymes such as phospholipase D and phospholipase A2 to produce phospholipids and other hydrolyzed lecithin products (See col. 4, ln 24-44); in a separate reaction, hydrolyzing triglycerides with digestive enzymes

such as 1- and 3-site selective lipase to produce a glyceride mixture of mono-, di-, and triglycerides (See col. 6, ln 24-57); and combining the hydrolysis products to produce the edible oil and fat composition (See col. 6, ln 56-62). Yasukawa et al teach the phospholipid component of the final composition should comprise about 0.1 to 30% by weight, preferably 0.3 to 20% by weight phospholipid (See col. 6, ln 56-62). Though Yasukawa et al teach hydrolyzing the lecithin and triglycerides separately, and then combining the hydrolyzed products, it would have been obvious to one of ordinary skill in the art at the time the invention was made to alternatively combine the lecithin and triglyceride, and then add, either simultaneously or sequentially, the enzymes used to hydrolyze the products. See teachings above.

Though Yasukawa et al are silent on the nature of the solvent used to perform the hydrolysis of the lecithin and triglycerides, it would have been obvious to one of ordinary skill in the art to use either an aqueous or an aprotic organic solvent, such as hexane, for phospholipases and lipase retain their function in either type solvent. In support, Sas et al teaches hydrolysis of lecithin with lipase and phospholipase A2 in an aqueous solvent medium (See Sas et al, col. 1, ln 45-62). Hattori et al teach that phospholipase A1 may perform phospholipid hydrolysis in hexane (see Hattori et al, col. 12, ln 20-26). Haas et al teach lipase hydrolyzes phospholipids in aqueous solutions, as well as aprotic organic solvents, including hexane (See Haas et al, Pg. 521, col. 2 and Pg. 423, col. 2). And Chung et al teach phospholipase A2 also performs hydrolysis of phospholipids in organic solvents (See Chung et al, col. 4, ln 35-42). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made carry out the hydrolysis of lecithin and triglycerides of Yasukawa et al in using phospholipase A1, A2, C, D and/or lipases, and in any order and in combination in an organic solvent, such as hexane (Claims 7-10, 18, 19 and 22-24). One would alternatively be motivated to perform the enzymatic contact in aqueous solvent, and would similarly expect success, because Sas et al teach successfully hydrolyzing lecithin in an aqueous solvent. One would have been motivated to perform the contact in an organic solvent because extraction of lecithin material from oil seeds is often performed through solubilization of the native

lecithin in an organic solvent; by performing the enzymatic contact in the organic solvent one saves the step of evaporating the organic solvent before hydrolyzing the lecithin. One would expect success because all the enzymes are effective in organic solvents, as taught by Hattori et al, Haas et al, and Chung et al.

Finally, the concentration of lecithin (phospholipid component) used in the composition of Yasukawa et al, the acetone insoluble content and the acid value of the hydrolyzed lecithin product produced in the method of Yasukawa et al, or in a method similar to that of Yasukawa et al wherein any of the enzymes phospholipases A1, A2, C, D and/or lipase, in any combination and order, as described above, are result effective variables that would be routinely optimized by one of ordinary skill in the art. The concentration of lecithin used to produce the edible oil and fat composition directly effects the concentration of the phospholipid component in the final composition. While Yasukawa et al teach 0.1 to 30% phospholipid in the final concentration, they are silent on the original concentration of lecithin used in making the composition (it appears applicant is referring to lecithin as the 'phospholipid component' and not the actual concentration of hydrolyzed phospholipids, as is Yasukawa et al); however, it would have been obvious to one of ordinary skill in the art to optimize the concentration of lecithin (which applicant calls phospholipid component) to product the desired phospholipid concentration in the end product. Generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical or produces unexpected results. Where the general conditions of a claim are disclosed by the prior art it is not inventive to discover the optimum or workable ranges by routine experimentation, See *In re Aller,* 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Also note that where the claimed ranges overlap or lie inside ranges disclosed by the prior art a prima facie case of obviousness exists. See *In re Wertheim,* 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990) (Claims 2, 3, 20 and 21). Similarly, the acid value is a direct result of the reaction time

and the degree of hydrolysis that occurs. Additionally, the acetone insoluble content is representative of the amount of phospholipids present in the lecithin material; depending on the purity of the native lecithin, the percentage of phospholipids initially present in the material, and the degree of hydrolysis by phospholipase C (which removes the phosphatidyl group from the phospholipid) and non-specific lipases (which can also hydrolyze the ester bond between the glycerol backbone and the phosphatidyl group), the acetone insoluble content can be altered. Therefore, by increasing the phospholipid content of the starting lecithin material, by purification, or by purchasing a lecithin material with a desired high acetone insoluble content, and by eliminating the use of phospholipase C, one of ordinary skill in the art can increase the acetone insoluble content to above 60% (Claims 16, 17, 27 and 28).

Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 11-13, 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yasukawa et al (US Patent 4,976,984), in view of Hattori et al (US Patent 5,378,623), Haas et al (J. Am. Oil Chem. Soc, 1995) and Chung et al (US Patent 6,773,902), further in view of Jirjis et al (US 2003/0072856 A1).

Yasukawa et al teach a method for making an edible oil and fat composition comprising phospholipids and a glyceride mixture, wherein the glyceride mixture comprises diglycerides, monoglycerides and triglycerides, the method comprising hydrolyzing natural lecithins with enzymes such as phospholipase D and phospholipase A2 to produce phospholipids and other hydrolyzed lecithin products (See col. 4, ln 24-44); in a separate reaction, hydrolyzing triglycerides with digestive enzymes such as 1- and 3-site selective lipase to produce a glyceride mixture of mono-, di-, and triglycerides (See col. 6, ln 24-57); and combining the hydrolysis products to produce the edible oil and fat composition (See col. 6, ln 56-62). Yasukawa et al teach the phospholipid component of the final composition should comprise about 0.1 to 30% by weight, preferably 0.3 to 20% by weight phospholipid (See col. 6, ln 56-

62). Though Yasukawa et al teach hydrolyzing the lecithin and triglycerides separately, and then combining the hydrolyzed products, it would have been obvious to one of ordinary skill in the art at the time the invention was made to alternatively combine the lecithin and triglyceride, and then add, either simultaneously or sequentially, the enzymes used to hydrolyze the products. See teachings above.

Additionally, though Yasukawa et al only teach the use of lipase and phospholipases A2 and D, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use any enzyme that effectively hydrolyzes an ester bond in a phospholipid, including phospholipases A1, A2, C, D, and/or lipase (See Hattori et al, col. 1, ln 11-28). Additionally, it would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the contact in either an aqueous solvent or in an organic solvent medium, such as hexane, since all the enzymes will effectively hydrolyze phospholipids in either type of solvent. See teachings above.

Though neither Yasukawa et al nor Hattori et al teach obtaining the lecithin material through a membrane degumming process, it would have been obvious to one of ordinary skill in the art at the time the invention was made to obtain the native lecithin by performing a membrane degumming process and collecting the retentate, such as taught by Jirjis et al (Claims 11 and 25). Jirjis et al teach a method of obtaining lecithin material as a by-product of a membrane degumming processes of soybean oil, comprising processing oil seeds to produce crude vegetable oil, dissolving the crude vegetable oil in a hydrocarbon solvent to produce vegetable oil miscella, feeding the solution comprising the miscella to a series of membranes, and recovering the retentate (stream that does not pass through the membrane) from the second phospholipid filter (permeated through first phospholipid filter that filter out large solids, does not permeate through second phospholipid filters that filter out phospholipids); this retentate comprises a lecithin product containing up to 85% phospholipids (See Jirjis et al Pg. 2, paragraphs 0012-0013 and Pg 4, paragraph 0033-0037).

One of ordinary skill in the art would have been motivated to obtain the lecithin as the retentate from a membrane degumming process, such as that taught by Jirjis et al, in the method of Yasukawa et al because the membrane filters out the large solid impurities, thereby making the lecithins obtained via the membrane degumming process have fewer impurities than lecithins obtained by water degumming processes. One would have been motivated to obtain a lecithin material with a high concentration of phospholipids by performing the membrane degumming process of Jirjis et al because Yasukawa et al's process is specifically designed to hydrolyze lecithin phospholipids, therefore a higher concentration of phospholipids in the starting lecithin material would equate to a greater amount of hydrolyzed phospholipids in the method of Yasukawa et al. One would have expected success because using the lecithin obtained from the retentate of the membrane degumming process of Jirjis et al in the method of Yasukawa et al because Yasukawa et al's method utilizes lecithin, how the lecithin material is obtained does not effect the method or the outcome.

Furthermore, though Yasukawa et al, Hattori et al, Chung et al nor Haas et al teach performing the method of hydrolyzing the lecithins, either in aqueous or organic solvent medium, in the presence of a membrane effective to separate the hydrolyzed phospholipids, monoglycerides, and diglycerides from the released fatty acids, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the membrane system of Jirjis et al to effectively separate the smaller, released fatty acids from the desired hydrolyzed phospholipids, mono- and diglycerides (Claims 12, 13 and 26). One of ordinary skill in the art would have been motivated to filter out the released fatty acids via a membrane filtration system in order to obtain a retentate of hydrolyzed phospholipids and mono- and diglycerides because these fats and oils are desirable for uses in the food and pharmaceutical industries, such as for the edible oil and fat composition of Yasukawa et al, while the released fatty acids are not. One would have expected success because Jirjis et al teach a simple system of membranes that can effectively separate out molecules based on molecular size and weight; therefore the smaller, lighter released fatty acids could be

filtered out of a solution comprising the fatty acids and the larger hydrolyzed lecithins, leaving only the hydrolyzed lecithins as the desired retentate.

Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 30-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bojsen et al (US 2003/0175383), in view of Haas et al (J. of the Am. Oil Chem. Soc., 1995) and/or Jirjis et al (US 2003/0072856 A1).

Bojsen et al teach a method of preparing a flour dough, which comprises a phospholipid component and a triglyceride component, by contacting the flour dough with a lipolytic acyl hydrolase (LAH E.C. 3.1.1.26) (See Pg. 2-3, paragraph 0042). LAH is a lipase that effectively hydrolyzes phospholipids, including phosphatidylcholine (lecithin) to create hydrolyzed phospholipids, but does not hydrolyze the triglyceride or 1-monoglyceride components of the flour dough (See Pg. 2-3, paragraph 0042 and Pg. 3 paragraph 0057-0058.

Though Bojsen et al are silent on are silent on the nature of the solvent used to perform the hydrolysis of the phospholipids in the flour dough, it would have been within the purview of one skilled in the art, at the time the invention was made, to perform the hydrolysis in an aqueous or in an organic solvent medium (Claim 30). Though Bojsen et al do not teach the specific nature of the new LAH enzyme, it is known that lipases are functional in both aqueous and organic solvents (See, e.g. Haas et al, Pg. 521 and 521, col. 2). One of ordinary skill in the art would have been motivated to perform the hydrolysis in an organic solvent because Haas et al teach that phospholipids exhibit increased solubility and reduced viscosity in organic solvents compared to aqueous systems (See Haas et al, Pg. 519, col. 2). Therefore, one of ordinary skill in the art would have had at least a reasonable expectation of successfully performing the hydrolysis of Bojsen et al in either an aqueous or organic solvent.

Regarding the exact concentration of the phospholipids in the flour dough (which applicant calls the phospholipid component in the lecithin material) and the concentration of acetone insoluble materials present in the hydrolyzed lecithin product and the acid value of the hydrolyzed lecithin product, Bojsen et al is silent on these parameters. However, these concentrations and acid values are result effective variables that would be routinely optimized by one of ordinary skill in the art. The concentration of the phospholipids in the flour dough depends on the type of flour chosen to produce the bread; the concentration and make-up of the dough varies based on the source and differentially affects the taste and texture of the final bread product. Therefore, one skilled in the art could choose a bread flour with the desired concentration of phospholipids in order to produce the desired final bread product (Claims 32 and 33). Generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical or produces unexpected results. Where the general conditions of a claim are disclosed by the prior art it is not inventive to discover the optimum or workable ranges by routine experimentation, See *In re Aller,* 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Also note that where the claimed ranges overlap or lie inside ranges disclosed by the prior art a prima facie case of obviousness exists. See *In re Wertheim,* 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). Similarly, the acid value is a direct result of the reaction time and the degree of hydrolysis that occurs. Additionally, the acetone insoluble content is representative of the amount of phospholipids present in the lecithin material; depending on the purity of the native lecithin present in the flour, the percentage of phospholipids initially present in the material other and non-specific lipases (which can also hydrolyze the ester bond between the glycerol backbone and the phosphatidyl group), thus the acetone insoluble content can be altered and optimized by routine experimentation to produce a final bread product with the desired acid value and taste. By increasing the phospholipid content of the starting lecithin material, by purification, or by purchasing a lecithin material with a desired high acetone

insoluble content, one of ordinary skill in the art can increase the acetone insoluble content to above 60% (Claims 35 and 36).

Additionally, though Bojsen et al do not teach obtaining the lecithin material through a membrane degumming process, it would have been obvious to one of ordinary skill in the art at the time the invention was made to obtain native lecithin by performing a membrane degumming process and collecting the retentate, such as taught by Jirjis et al, such lecithin (comprising phospholipids) could be added to the dough flour of Bosjen et al in order to increase the phospholipid content to improve the taste (Claim 31). Jirjis et al teach a method of obtaining lecithin material as a by-product of a membrane degumming processes of soybean oil, comprising processing oil seeds to produce crude vegetable oil, dissolving the crude vegetable oil in a hydrocarbon solvent to produce vegetable oil miscella, feeding the solution comprising the miscella to a series of membranes, and recovering the retentate (stream that does not pass through the membrane) from the second phospholipid filter (permeated through first phospholipid filter that filter out large solids, does not permeate through second phospholipid filters that filter out phospholipids); this retentate comprises a lecithin product containing up to 85% phospholipids (See Jirjis et al Pg. 2, paragraphs 0012-0013 and Pg 4, paragraph 0033-0037).

One of ordinary skill in the art would have been motivated to obtain the lecithin as the retentate from a membrane degumming process, such as that taught by Jirjis et al, for the dough flour of Bosjen et al because the membrane filters out the large solid impurities, thereby making the lecithins obtained via the membrane degumming process have fewer impurities than lecithins obtained by water degumming processes. One would have been motivated to add a lecithin material with a high concentration of phospholipids by performing the membrane degumming process of Jirjis et al because Bosjen et al's process is specifically designed to hydrolyze lecithin phospholipids, therefore a higher concentration of phospholipids in the starting dough flour would equate to a greater amount of hydrolyzed phospholipids in the final product of Bosjen et al. One would have expected success because using the lecithin obtained

from the retentate of the membrane degumming process of Jirjis et al in the method of Bosjen et al because Bosjen et al's method utilizes lecithin, how the lecithin material is obtained does not effect the method or the outcome. Still further, it would have been obvious to one of ordinary skill in the art to perform the hydrolysis of the dough flour in the presence of a membrane system, such as that of Jirjis et al (Claim 34). The membrane system of Jirjis et al effectively separates the smaller, released fatty acids from the desired hydrolyzed phospholipids, mono- and diglycerides; it is mono and diglycerides that are desired in food products, not the fatty acids. One of ordinary skill in the art would have been motivated to filter out the released fatty acids via a membrane filtration system in order to obtain a retentate of hydrolyzed phospholipids and mono- and diglycerides because these fats and oils are desirable for uses in the food and pharmaceutical industries, such as for the edible oil and fat composition of Yasukawa et al, while the released fatty acids are not. One would have expected success because Jirjis et al teach a simple system of membranes that can effectively separate out molecules based on molecular size and weight; therefore the smaller, lighter released fatty acids could be filtered out of a solution comprising the fatty acids and the larger hydrolyzed lecithins, leaving only the hydrolyzed lecithins as the desired retentate.

Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allison M. Ford whose telephone number is 571-272-2936. The examiner can normally be reached on 7:30-5 M-Th, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Allison M Ford
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PRIMARY EXAMINER